

(1) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 375mg of nicotinic acid and having:

5 a nicotinic acid Cmax of about 3 $\mu$ g/ml;

a nicotinic acid Tmax in the range of between about 5.6 hours and about 6 hours; and

an AUC for nicotinic acid of about 6 $\mu$ ghr/ml.

(2) An intermediate release nicotinic acid formulation of claim 1, wherein said nicotinic acid formulation is a tablet.

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(3) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 375mg of nicotinic acid and having:

- a nicotinuric acid C<sub>max</sub> of about 2µg/ml;
- a nicotinuric acid T<sub>max</sub> in the range of between about 5.6 hours and about 6 hours; and
- an AUC for nictoinuric acid of about 10µghr/ml.

(4) An intermediate release nicotinic acid formulation of claim 3, wherein said nicotinic acid formulation is a tablet.

(5) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 500mg of nicotinic acid and having:

5 a nicotinic acid Cmax in the range of from between about 1µg/ml and 10µg/ml;  
a nicotinic acid Tmax in the range of between about 5.6 hours and about 6 hours; and  
an AUC for nicotinic acid in the range of from between about 2µghr/ml and about 34µghr/ml.

(6) An intermediate release nicotinic acid formulation of claim 5, wherein the Cmax has a mean of about 4µg/ml and the AUC has a mean of about 9µghr/ml.

(7) An intermediate release nicotinic acid formulation of claim 5, wherein said nicotinic acid formulation is a tablet.

(8) An intermediate release nicotinic acid formulation of claim 6, wherein said nicotinic acid formulation is a tablet.

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(9) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 500mg of nicotinic acid and having:

5 a nicotinuric acid C<sub>max</sub> in the range of from between about 2µg/ml and 3µg/ml;  
a nicotinuric acid T<sub>max</sub> in the range of between about 5.6 hours and about 6 hours; and  
an AUC for nicotinuric acid in the range of from between about 6µghr/ml and about 16µghr/ml.

(10) An intermediate release nicotinic acid formulation of claim 9, wherein the C<sub>max</sub> has a mean of about 2µg/ml and the AUC has a mean of about 9µghr/ml.

(11) An intermediate release nicotinic acid formulation of claim 9, wherein said nicotinic acid formulation is a tablet.

(12) An intermediate release nicotinic acid formulation of claim 10, wherein said nicotinic acid formulation is a tablet.

(13) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 750mg of nicotinic acid and having:

5 a nicotinic acid Cmax in the range of from between about 8µg/ml and 9µg/ml;  
a nicotinic acid Tmax in the range of between about 5.6 hours and about 6 hours; and  
an AUC for nictoinic acid in the range of from between about 21µghr/ml and about 22µghr/ml.

(14) An intermediate release nicotinic acid formulation of claim 13, wherein the Cmax has a mean of about 8µg/ml and the AUC has a mean of about 21µghr/ml.

(15) An intermediate release nicotinic acid formulation of claim 13, wherein said nicotinic acid formulation is a tablet.

(16) An intermediate release nicotinic acid formulation of claim 14, wherein said nicotinic acid formulation is a tablet.

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(17) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 750mg of nicotinic acid and having:

- a nicotinuric acid Cmax in the range of from between about 3 $\mu$ g/ml and 3.2 $\mu$ g/ml;
- a nicotinuric acid Tmax in the range of between about 5.6 hours and about 6 hours; and
- an AUC for nicotinuric acid in the range of from between about 11 $\mu$ ghr/ml and about 13 $\mu$ ghr/ml.

(18) An intermediate release nicotinic acid formulation of claim 17, wherein the Cmax has a mean of about 3 $\mu$ g/ml and the AUC has a mean of about 12 $\mu$ ghr/ml.

(19) An intermediate release nicotinic acid formulation of claim 17, wherein said nicotinic acid formulation is a tablet.

(20) An intermediate release nicotinic acid formulation of claim 19, wherein said nicotinic acid formulation is a tablet.

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(21) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 1000mg of nicotinic acid and having:

a nicotinic acid Cmax in the range of from between about 9µg/ml and 17µg/ml;

a nicotinic acid Tmax in the range of between about 5.6 hours and about 6 hours; and

an AUC for nicotinic acid in the range of from between about 24µghr/ml and about 43µghr/ml.

(22) An intermediate release nicotinic acid formulation of claim 21, wherein the Cmax has a mean of about 13µg/ml and the AUC has a mean of about 33µghr/ml.

(23) An intermediate release nicotinic acid formulation of claim 21, wherein said nicotinic acid formulation is a tablet.

(24) An intermediate release nicotinic acid formulation of claim 22, wherein said nicotinic acid formulation is a tablet.

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(25) An intermediate release nicotinic acid formulation suitable for oral administration once-a-day for treating hyperlipidemia without causing drug-induced hepatotoxicity to a level which would require use of said intermediate release nicotinic acid formulation to be discontinued, said intermediate release nicotinic acid formulation containing at least about 1000mg of nicotinic acid and having:

a nicotinuric acid C<sub>max</sub> in the range of from between about 3µg/ml and 5µg/ml;

a nicotinuric acid T<sub>max</sub> in the range of between about 5.6 hours and about 6 hours; and

an AUC for nicotinuric acid in the range of from between about 12µghr/ml and about 19µghr/ml.

(26) An intermediate release nicotinic acid formulation of claim 25, wherein the C<sub>max</sub> has a mean of about 4µg/ml and the AUC has a mean of about 15µghr/ml.

(27) An intermediate release nicotinic acid formulation of claim 25, wherein said nicotinic acid formulation is a tablet.

(28) An intermediate release nicotinic acid formulation of claim 26, wherein said nicotinic acid formulation is a tablet.